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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,238	05/08/2000	CORNELIA BERGHOF	2727-102	8813

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EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

304

Office Action Summary

Application No.

09/508,238

Applicant(s)

BERGHOF ET AL.

Examiner

Jehanne Souaya Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-50, 52-56 and 58-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46-50, 56 and 60 is/are allowed.
- 6) ☐ Claim(s) 58, 59, 61-64 and 66-78 is/are rejected.
- 7) ☒ Claim(s) 52-55 and 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 46-50, 51-56, and 58-78 are pending in the instant application. Claims 65-78 are newly added. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either applied as necessitated by the claim amendments. They constitute the complete set being presently applied to the instant Application. This action is NON-FINAL.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. All objections and rejections made in the previous office action, mailed 11/19/2003 are moot in view of the amendments to the claims.

Claim Objections

4. Claims 52-55, and 65 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims from which claims 52-55 depend recite nucleic acid molecules "consisting of" specific sequences. Such language is considered closed, and as such, the nucleic acid molecules cannot be added to or changed, as in claims 52-55. It is suggested that claim 46 be amended to read, for example: "An isolated polynucleotide

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consisting of 30 contiguous nucleotides of SEQ ID NO: 1, or the complement of SEQ ID NO: 1, wherein the polynucleotide is DNA, RNA, or PNA, and wherein the polynucleotide optionally consists of i) a moiety that produces a signal, or ii) a binding site for a moiety that produces a signal, when the polynucleotide hybridizes to *Pseudomonas* DNA.” It is suggested that each of claims 47-50 also be amended as set forth above to overcome the objections to claims 52-55 and 65.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 58, 61-63 and 68-78 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 58 and 68 recite steps that can be considered mental steps. The recitation of “determining”, “comparing” and “selecting” are words that can be used to denote mental steps. Methods that only recite steps which encompass mental steps are non statutory subject matter. It is suggested that the claims be amended to recite active positive steps. The limitations in dependent claims 61-63 and 69-78 recite latent characteristics of nucleic acids and do not set forth any positive, active steps.

Claim Rejections - 35 USC § 112

7. Claim 75 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a New Matter Rejection. The claim recites “wherein the nucleic acid sequence of b) is at least 250 nucleotides”, however the specification does not teach or contemplate nucleic acids as probes or primers that are longer than 250 in length. Also, SEQ ID NO: 1 is only 131 nucleic acids in length. While the specification contemplates nucleic acids that are 10-250 nucleotides in length, the recitation of “at least 250” represents a broadening of the scope set forth in the specification.

8. Claims 58, 59, 61-64, 66, and 67 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58-59 are indefinite in the recitation of “a polynucleotide comprising 10-250 contiguous nucleotides of SEQ ID NO: 1” because SEQ ID NO: 1 is only 131 nucleotides long. It is unclear, therefore, how a polynucleotide could have 250 contiguous nucleotides of a 131 nucleotide molecule. The following language is suggested: “a polynucleotide comprising 10 or more contiguous nucleotide of SEQ ID NO: 1, wherein the polynucleotide is 10-250 nucleotides long”.

Claim 66 is indefinite as the claim recites “the method of claim 56” whereas claim 56 is drawn to a kit. Therefore, it is unclear if the claim is intended to be drawn to a method or to a kit.

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Claim 66 is indefinite at the recitation of “probe” lacks sufficient antecedent basis. Claim 56 does not recite a probe. If claim 66 is intended to be drawn to a kit and dependent from claim 56, it is suggested that the recitation of “primer or probe” be changed to --polynucleotide--.

Claim Rejections - 35 USC § 103

9. Claims 68 and 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Heidrich et al (hereinafter referred to as Heidrich; US Patent 6,194,145), Rijpkema et al (hereinafter referred to as Rijpkema; J. Clin. Microb. Vol. 33, pages 3091-3095, 1995), Tyler et al (hereinafter referred to as Tyler, Clinical and Diagnostic Laboratory Immunology; vol. 2, pages 448-453, 1995), Kur et al (hereinafter referred to as Kur; Acta Microbiologica Polonica, vol 44, pages 111-117, 1995) and Jensen (WO 93/11264).

Heidrich teaches the detection and differentiation of Legionella species using genus specific primers and species specific probes that differentiate between the polymorphic regions of the 23S-5S intergenic spacer region of different Legionella species (see abstract, example 3, cols3-4, 8). Heidrich teaches preferred lengths and types of probes.

Rijpkema teaches the detection and genotyping of three genomic groups of Borrelia burgdorferi using polymorphic regions between the 23S-5S intergenic spacer region. Rijpkema teaches the ability to distinguish between species using species specific primers and between groups using group specific probes (see abstract, table 2, page 3094).

Jensen teaches that prokaryotic organisms contain hypervariable spacer regions between the 16S and 23S and between the 23S and 5S ribosomal sequences at the genus and species level (see page 11, lines 18-22).

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Kur teaches that *Pseudomonas aeruginosa* is associated with a high mortality rate and is resistant to a wide spectrum of antibiotics (see para bridging pages 111-112). Kur teaches that phenotypic description does not necessarily provide unambiguous identification of strains of the species and that more precise methods are required. Kur teaches a schematic diagram indicating the areas of hypervariability in organisms which includes the 23S-5S spacer region (see figure 1). Kur demonstrates identification of *P. aeruginosa* using primers to the 16S-23S genes.

Tyler demonstrates the design of species specific primers and probes for differentiation of pathogenic pseudomonads on the basis of amplifying and sequencing the 16S-23S intergenic spacer between species of pseudomonas and detecting regions of variability for targeting with species specific probes and primers (see page 448, col. 2, and page 449).

At the time the invention was made the following information and teachings were available to the ordinary artisan 1) that the 23S-5S intergenic region between bacteria contained variable regions and that such regions could be exploited to detect and differentiate different species of organisms, 2) that precise methods of identifying *P. aeruginosa* and differentiating between pathogenic species of *P. aeruginosa* were required, and 3) that the 16S-23S intergenic spacer hypervariability was exploited for differentiation among *Pseudomonas* species, and that the 23S-5S intergenic region had been used to differentiate among species of bacteria.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to sequence the 23S-5S intergenic region (ITS) of pseudomonas species and to detect regions of variability for the purpose of constructing genus and species specific probes and primers based on the differences between the ITS for the purpose of detecting and differentiating *P. aeruginosa* as taught by Heidrich, Rijpkema, Kur, Jensen, and Tyler. The

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ordinary artisan would have been motivated to develop probes and primers for detecting *P. aeruginosa* based on the teachings of Heidrich, Rijpkema, Kur, Jensen, and Tyler as set forth above, because Kur teaches that *Pseudomonas aeruginosa* is associated with a high mortality rate and is resistant to a wide spectrum of antibiotics and that phenotypic description does not necessarily provide unambiguous identification of strains of the species and that more precise methods are required. The ordinary artisan would have had a reasonable expectation of success that the 23S-5S ITS of *Pseudomonas* contained regions of variability between species because both Jensen and Kur teach that bacteria possess such variability in the 23S-5S and Heidrich and Rijpkema further demonstrate that such can be used for the identification and differentiation of different species of bacteria. Additionally, Tyler teaches that such regions were exploited in the 16S-23S ITS for differentiation among species of *Pseudomonas* but that some primers only detected a certain percentage of isolates (see page 452, col. 1). Therefore, the ordinary artisan would have been further motivated to develop species probes and primers that would distinguish between species of *Pseudomonas* and to detect *Pseudomonas aeruginosa* using the 5S-23S intergenic region of *Pseudomonas* for the purpose of developing primers and probes that could be used to detect and differentiate as many species or isolates as possible.

Conclusion

10. Claims 46-50, 56, and 60 are allowable.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-

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0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jehanne Sitton
Primary Examiner
Art Unit 1634

7/12/04